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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,437	11/30/2004	Scott Manzo	2843	2942
Covidien 60 Middletown Avenue North Haven, CT 06473			EXAMINER HUANG, LIAN	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 08/13/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/516,437

Applicant(s)

MANZO, SCOTT

Examiner

LIAN HUANG

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on **9 June 2009** has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1- 6, 8-15, 17-19, and 22-25 are rejected under 35 U.S.C. 102(b) as being disclosed by **Yencho et al. (US 6,206,913)**.

Regarding claim 1, Yencho et al. disclose an apparatus for performing a surgical anastomosis, comprising:

a tubular sleeve (**134**) defining an axial lumen therethrough;

a positioning tube (**136**) defining an axial lumen therethrough, the positioning tube being configured and adapted to be slidably received within the axial lumen of the tubular sleeve (figure 28A);

an expansion assembly having a tubular body and an expandable tip operatively coupled to a distal end thereof, the expandable tip having a retracted position in which the expandable tip can pass through the axial lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube (**148**, column 13, lines 14-16, where it is implied that **148** cannot pass through the axial lumen of the positioning tube, since it is deflated before sliding proximally for removal); and

an anchoring-assembly including:

a flange member (**122**) having a head portion and an expandable annular body integrally coupled to the head portion, the annular body defining a passage (figure 29), the passage extending through the head portion and the annular body; and

a locking member (**111**) defining a lumen therethrough,

wherein the annular body of the flange member is movable between an unexpanded configuration when the locking member is outside the passage of the annular body (figure 17) and a radially expanded configuration upon insertion of the locking member into the passage of the annular body (figure 20).

Regarding claim 2, Yencho et al. disclose an apparatus as stated above wherein the expandable tip of the expansion assembly is a balloon (**148**).

Regarding claim 3, Yencho et al. disclose an apparatus as stated above wherein the annular body of the anchoring assembly comprises at least a pair of diametrically opposed longitudinal slots formed therein, wherein the annular body is

expandable along the pair of longitudinal slots (**116**, please compare figure 28E and 28F).

Regarding claim 4, Yencho et al. disclose an apparatus as stated above wherein the annular body of the anchoring assembly includes a plurality of protuberances formed on an outer surface thereof (figure 16).

Regarding claim 5, Yencho et al. disclose an apparatus as stated above wherein the annular body of the anchoring has a first radius when not expanded radius and second radius, larger than the first radius, when expanded (figure 15, where **115** is expanded and **116** is not yet expanded, and the radius of **115** is greater than that of **116**).

Regarding claim 6, Yencho et al. disclose an apparatus as stated above wherein the head portion of the flange member (**122**) has a radius which is larger than the first radius of the annular body (figure 28F).

Regarding claim 8, Yencho et al. disclose an apparatus as stated above wherein the longitudinal slots extend through a proximal terminal end of the annular body and terminate at a distance spaced from the head portion (**116**, figure 28E).

Regarding claim 9, Yencho et al. disclose an apparatus as stated above wherein the head portion includes a plurality of protuberances formed on a proximal surface thereof (**122**, figure 29).

Regarding claim 10, Yencho et al. disclose an apparatus as stated above wherein the head portion includes a tapered distal surface (**147**).

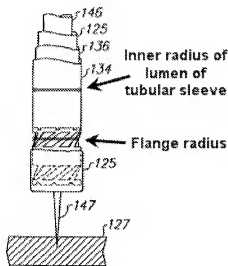
Regarding claim 11, Yencho et al. disclose an apparatus as stated above wherein the annular body of the anchoring assembly comprises a plurality of longitudinal slots formed therein (figure 24).

Regarding claim 12, Yencho et al. disclose an apparatus as stated above wherein the annular body of the anchoring assembly comprises at least one helical slot (where "helical" is taken to mean "having a shape approximating that of a helix") extending through (figure 24, where "through" is taken to mean "up to and including"; please refer to the figure below) the terminal end of the annular body.

Regarding claim 13, Yencho et al. disclose an apparatus as stated above wherein a proximal end of the locking member (111) is configured and adapted to engage a distal end of the positioning tube (136, figure 24).

Regarding claim 14, Yencho et al. disclose an apparatus as stated above wherein the head portion of the flange member (122) has a radius which is larger than a radius of the lumen of the tubular sleeve (figure 28F).

Regarding claim 15, Yencho et al. disclose an apparatus as stated above wherein the head portion of the flange member (122) has a radius which is smaller than an inner radius of the lumen of the tubular sleeve (134; figure 24, please refer to the figure below).



Regarding claim 17, Yencho et al. disclose a method for performing a surgical anastomosis, comprising the steps of: providing an apparatus for performing an the surgical anastomosis, the apparatus comprising:

a tubular sleeve (134) defining an axial lumen therethrough;

a positioning tube (136) defining an axial lumen therethrough, the positioning tube being configured and adapted to be slidably received within the axial lumen of the tubular sleeve;

an expansion assembly having a tubular body and an expandable tip operatively coupled to a distal end thereof, the expandable tip having a retracted position in which the expandable tip can pass through the axial lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube (148, column 13, lines 14-16, where it is implied that 148 cannot pass through the axial lumen of the positioning tube, since it is deflated before sliding proximally for removal); and

an anchoring assembly including:

a flange member (**122**) having a head portion and an expandable annular 25 body integrally coupled to the head portion, the flange member defining a passage extending through the head portion and the annular body; and

a locking member (**111**) arranged to be received in the passage of the flange member (figure 29), the locking member defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body (where "within" is taken to mean "inside the limits of");

passing the apparatus through a body lumen and through an opening in a body vessel such that the head portion of the flange member of the anchoring assembly is positioned within the body vessel (figure 28E);

advancing the expansion assembly through the positioning tube such that the expandable tip is within the body vessel;

expanding the expandable tip within the body vessel (figures 28C and 28D);

withdrawing the tubular body of the expansion assembly to press the head portion of the flange member of the anchoring assembly against the body vessel and to approximate the body vessel with the body lumen until the annular body of the flange member of the anchoring assembly is positioned within a distal end of the body lumen;

advancing the positioning tube through the tubular body to drive the locking member of the anchoring assembly into the annular body of the flange member and to

deflect the annular body radially outward against the inner surface of the body lumen (figures 28A-H, column 11, lines 1-24).

Regarding claim 18, Yencho et al. disclose a method as stated above further comprising the step of retracting the expandable tip of the expansion assembly (column 13, lines 14-16).

Regarding claim 19, Yencho et al. disclose a method as stated above further comprising the step of withdrawing the tubular body (**134**), the positioning tube (**136**) and the expansion assembly (**148**) from the body lumen (column 13, lines 14-16, where **134** and **136** are part of **131** (column 11, lines 45-51)).

Regarding claim 22, Yencho et al. disclose an anchoring assembly for use in a surgical anastomosis procedure, comprising:

a flange member (**122**) having a head portion and an expandable annular body integrally coupled to the head portion, the flange member defining a passage extending through the head portion and the annular body; and

a locking member (**111**) discrete from the flange member (where "discrete" is taken to mean "distinct") and separable, the locking member defining a lumen therethrough, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body (where "within" is taken to mean "inside the limits of") such that the locking member is secured within the passage of the annular body (figure 20, where part 111 cannot extend or expand past part 122).

Regarding claim 23, Yencho et al. disclose an anchoring assembly as stated above wherein the annular body of the anchoring comprises at least a pair of diametrically opposed longitudinal slots formed therein, wherein the annular body is expandable along the pair of longitudinal slots (**116**, please compare figure 28E and 28F).

Regarding claim 24, Yencho et al. disclose an anchoring assembly wherein the annular body of the anchoring assembly has a first radius when not expanded and a second radius, larger than the first radius, when expanded (figure 15, where **115** is expanded and **116** is not yet expanded, and the radius of **115** is greater than that of **116**).

Regarding claim 25, Yencho et al. disclose an anchoring assembly wherein the head portion of the flange member (**122**) has a radius which is larger than the first radius of the annular body (figure 28F).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Yencho et al. (US 6,206,913)** in view of **Weadock (US 6,629,988 B2)**.

Regarding claim 16, Yencho et al. disclose an apparatus as stated above, but fails to teach it wherein the anchoring assembly is made from a bio-absorbable material.

However, Wendock teaches an anchoring assembly made from bioabsorbable material (**12**).

It would be obvious to one of ordinary skill in the art at the time of the invention to have the anchoring assembly be made from bioabsorbable material as taught by Wendock, since Wendock states that making the assembly with bioabsorbable material allows the assembly to be resorbed as the anastomosis heals (column 2, lines 43-60).

5. Claims 7, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Yencho et al. (US 6,206,913)** in view of **Evard et al. (US 6,206,913)**.

Regarding claim 7 and 26, Yencho et al. disclose an apparatus and assembly as stated above wherein the locking member (**111**) comprises a cylindrical body having a distal end portion, wherein the cylindrical body has a radius which is larger than the first radius of the annular body, but fails to teach it wherein the distal end portion of the cylindrical body tapers down to a radius which is smaller than the first radius of the annular body.

However, Evard et al. teach a cylindrical member between two flanges wherein the cylindrical body tapers (figures 1 and 2).

It would be obvious to one of ordinary skill in the art at the time of the invention to have the locking member taper as taught by Evard et al., since Evard et al. state that such a modification would maintain a minimum passageway diameter between the openings of the connected anatomical structures (column 3, lines 5-8).

Regarding claim 27, Yencho et al. disclose an anchoring assembly wherein the longitudinal slots extend the annular body and terminate at a distance spaced from the head portion (**116**, figure 24).

6. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Yencho et al. (US 6,206,913)** in view of **Edelstein (US 5,591,179)**.

Regarding claim 20, Yencho et al. disclose a method as stated above, but fails to teach it wherein the surgical anastomosis is a radical prostatectomy.

However, Edelstein teaches using the technique of anastomosis in radical prostatectomy (column 4, line 53).

It would be obvious to one of ordinary skill in the art at the time of the invention to apply the technique of anastomosis to radical prostatectomy as taught by Edelstein to expand the uses of Yencho et al. for the predictable result of enabling an additional method of performing radical prostatectomy.

Regarding claim 21, Yencho et al. disclose a method as stated above, but fails to teach it wherein the radical prostatectomy includes the steps of removing the prostate gland from between the urethra and the bladder to define a urethral stump and a bladder neck.

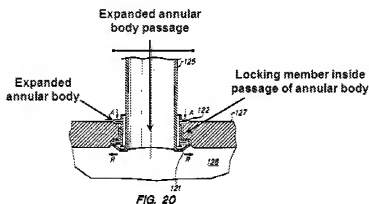
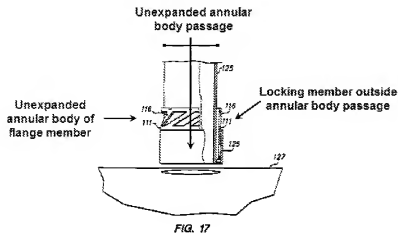
However, Edelstein teaches using the technique of removing the prostate gland to define a urethral stump and bladder neck (column 4, lines 51-62).

It would be obvious to one of ordinary skill in the art at the time of the invention to apply the technique of removing the prostate gland to radical prostatectomy as taught

by Edelstein to expand the uses of Yencho et al. for the predictable result of enabling an additional method of performing radical prostatectomy.

Response to Arguments

1. Applicant's arguments filed 9 June 2009 have been fully considered but they are not persuasive. Regarding claim 1, Yencho et al. disclose an invention wherein the annular body of the flange member (**122**) is movable between an unexpanded configuration when the locking member is outside the passage of the annular body (figure 17, please refer to the figure below).



and a radially expanded configuration upon insertion of the locking member into the passage of the annular body (figure 20, figure above). "Passage" is taken to mean a path along which something may pass." In this way, the passage of the annular body expands with its radial expansion, creating a passage that extends to the limit of the expanded position of the annular body. The locking member is thus within the passage. "Upon" is taken to mean "on the occasion of" so there is no direct causal relationship in the claim limitation.

2. For claim 17, positioning tube 136 secures the position of the locking member relative to the annular body as defined above, thereby meeting the limitations of the claim. "Discrete" is read as "distinct," so the proximal and distal ends of the stent 110 that are driven adequately meet the limitations to deflect flange 122. Expansion by relative rotation does not prevent the teachings of Yencho et al. from reading on the claim.
3. For arguments concerning claim 22, the added clause that the locking member is separable from the flange member does not distinguish the invention of the invention from that of the prior art since any members will be separable if enough force is applied to disconnect the parts.

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the locking member and flange member separable since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin b. Erlichman*, 169 USPQ 177, 179.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LIAN HUANG whose telephone number is (571)270-3987. The examiner can normally be reached on 7:30 AM-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
8/12/09